Clinical Trials in Russia

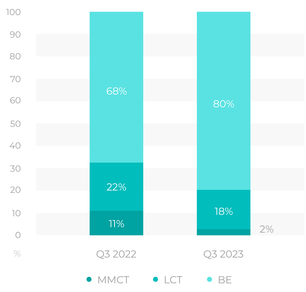
Q3 2023 Research report

Trial Data

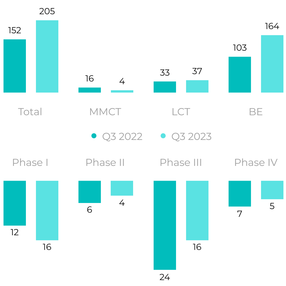
During Q3 2023 the Ministry of Health of the Russian Federation approved the start of 205 new clinical trials of all types, including local and bioequivalence studies. This represents a 35% year on year increase by the total number of studies.

The dominant type of clinical trials conducted across Russian sites in Q3 2023 were BE (Bio-equivalent Clinical Trials). The market share of BE studies raised from 68% to the unprecedent 80%. The market share of MMCTs (Multinational Multi-center Clinical Trials) collapsed from 11% to just 2% whilst the market share of Local Clinical Trials (LCTs) declined from 22% to 18%.

Percentage Breakdown of Clinical Trials by Type



Breakdown of Clinical Trials by Type and Phase

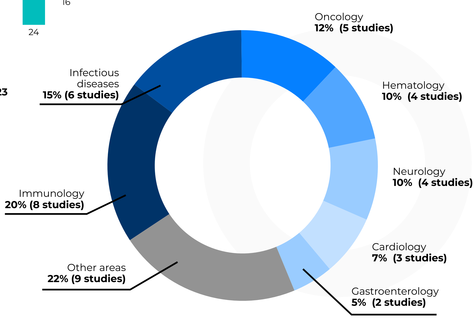


The most prevalent Phases of clinical trials conducted in Russian sites by total number of studies were both Phase I and Phase III – each with 39% share.

The largest number of clinical trials initiated in Russia during Q3 2023 were related to Immunology (8 studies), Infectious diseases (6 studies) and Oncology (5 studies). Other prominent therapy areas include Hematology, Neurology, Cardiology and Gastroenterology.

Breakdown of Clinical Trials in Russia in Q3 2023 by Therapeutic Area

More than one therapeutic area may be assigned to a trial. BE studies were not included in any therapeutic area group.



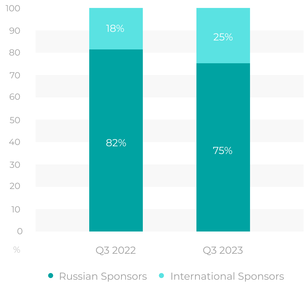
Sponsor Data

Clinical trials initiated in Russia during Q3 2023 were sponsored by pharmaceutical companies from Russia and 11 foreign countries. The combined market share of international pharmaceutical companies involved in the Russian Clinical trials market increased from 18% to 25% of all studies.

The dominant Phase of Clinical trials conducted across Russian sites by international pharmaceutical companies in Q3 2023 was Phase III with 13% share among Phase I – IV studies.

The most prevalent Sponsor's countries of origin in Q3 2023 were Russia (154 studies), India (23), Belarus (11) and Turkey (5). Other prominent countries include Hungary (3) and China (2).

Percentage Breakdown of Clinical Trials by Sponsor's Country of origin



Observational trials and trials without FDA-defined phases (from I to IV) were not counted in the following ranking.

Combined market share shown as a percentage of both international and Russian sponsors.

Top-10 International Trial Sponsors in Russia in Q3 2023

№	Company Name	Studies	Subjects
1	AstraZeneca	1	130
2	Giga Farm	1	120
3	Tonghua Anrate Biopharmaceutical	1	72
4	Lupin	1	60
5	Janssen	1	24
6	Bio-Thera Solutions	1	20
7	-	-	-
8	-	-	-
9	-	-	-
10	-	-	-
	Combined market share	**15%**	**7%**

Top-10 Russian Trial Sponsors in Russia in Q3 2023

№	Company Name	Studies	Subjects
1	Grotex	4	663
2	Gamaleya Research Institute	4	340
3	Generium	3	544
4	GeroPharm	3	266
5	Polysan	2	886
6	Promomed	2	160
7	Mabscale	1	494
8	Elta	1	462
9	R-Pharm	1	372
10	Materia Medica Holding	1	370
	Combined market share	**54%**	**72%**

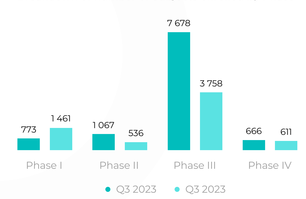
Combined market share shown as a percentage of both international and Russian sponsors. Bio-Equivalence (BE) studies were not included in this ranking.

Subject Data

The overall number of subjects enrolled (or planned to be enrolled) in clinical trials initiated in Russia during Q3 2023 reached a total of 6,366 subjects – a 37% drop in comparison with the previous year when 10,184 subjects were enrolled. The most prevalent Phase of clinical trials by the number of participating subjects was Phase III with 59% of all subjects enrolled.

Studies indicated by sponsors as Phase I-II were counted as Phase II; Phase II-III – as Phase III, Phase III-IV – as Phase IV.

Breakdown of number of Subjects enrolled by Phase



Clinical Trials in Russia

Q3 2023 Research report

Research Site Data

Top-5 Russian research sites (all studies) in Q3 2023

№	Site Name	City	No. Studies
1	Clinical Hospital № 9	Yaroslavl	25
2	I.M. Sechenov First Moscow State Medical University	Moscow	20
3	Yaroslavl Regional Clinical Narcological Hospital	Yaroslavl	18
4	Ecosafety	Saint-Petersburg	14
5	Clinical Hospital № 3	Yaroslavl	13
	Combined market share of these sites		44%

CRO Data

Top-10 CROs in Russia in Q3 2023 (Phase I - IV studies)

Observational Clinical trials and Clinical trials without FDA defined phases (from I to IV) were not included in this ranking.

№	Site Name	No. Studies	No. Subjects
1	Accellena	1	646
2	Benerix	1	494
3	OST Rus	1	312
4	Vita Aeterna	1	240
5	Medical Development Agency	1	200
6	MIK-Pharma	1	120
7	MDP-KIO	1	72
8	LABMGMU	1	38
9	Clinical Trials Center	1	36
10	-	-	-
	Combined market share	22%	34%

Top-5 CROs in Russia in Q3 2023 (BE studies)

Only BE (bioequivalence) studies were included in this ranking.

№	Site Name	No. Studies	No. Subjects
1	Probiotec Medical Center	11	481
2	AX Clinical Trials and Consulting	5	232
3	National Scientific Center for Research and Pharmacovigilance	4	170
4	OST Rus	3	210
5	Medical Development Agency	2	120
	Combined market share of these companies	15%	14%

Regulatory Data

During Q3 2023 the Center for Drug Evaluation and Research (CDER) of the U.S. FDA approved 38 new drugs, including 8 new molecular entities (NME); other approvals concerned new dosages, combinations or manufacturers.

Ten of these 38 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: FDA

Appr.Date	Drug (Active Ingredient)	Company
20.07.2023	Vanflytanda (Quizartinib Dihydrochloride)	Daiichi Sankyo
11.08.2023	Akeeganda (Abiraterone Acetate; Niraparib Tosylate)	Janssen
14.08.2023	Elrexfiobla (Elranatamab)	Pfizer
16.08.2023	Sohonosnda (Palovarotene)	Ipsen
16.08.2023	Abacavir; Dolutegravir; Lamivudinenda (Abacavir; Dolutegravir; Lamivudine)	Mylan
18.08.2023	Veopozbla (Pozelimab)	Regeneron
18.08.2023	Eylea (Aflibercept)	Regeneron
07.09.2023	Xalkorinda (Crizotinib)	PF Prism (Subsidiary of Pfizer)
26.09.2023	Bosulifnda (Bosutinib)	PF Prism (Subsidiary of Pfizer)
27.09.2023	Entyviobla (Vedolizumab)	Takeda

In Q3 2023 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) approved 25 new drugs including 1 generic, 1 biosimilar and 11 orphan medicines.

Eleven of these 25 drugs were tested (or being studied) in clinical trials involving Russian sites.

Source: EMA

Appr.Date	Drug (Active Ingredient)	Company
20.07.2023	Tepkinly (Epcoritamab)	AbbVie
20.07.2023	Inaqovi (Cedazuridine; Decitabine)	Otsuka
14.09.2023	Catiolanze (Latanoprost)	Santen Oy
14.09.2023	Olumiant (Baricitinib)	Eli Lilly
14.09.2023	Ryeqo (Relugolix; Norethisterone Acetate; Estradiol Hemihydrate)	Gedeon Richter
14.09.2023	Enhertu (Trastuzumab Deruxtecan)	Daiichi Sankyo
14.09.2023	Vanflyta (Quizartinib Dihydrochloride)	Daiichi Sankyo
14.09.2023	Zilbrysq (Zilucoplan)	UCB Pharma
14.09.2023	Adcetris (Brentuximab Vedotin)	Takeda
14.09.2023	Takhzyro (Lanadelumab)	Takeda
14.09.2023	Keytruda (Pembrolizumab)	Merck

FDA inspections

According to the U.S. FDA data, there were no FDA inspections conducted in a Russian investigative site during Q3 2023.

Roszdravnadzor inspections

According to the Roszdravnadzor quarterly report, as of 03/10/2023 there were no Regulatory inspections conducted by Roszdravnadzor during Q3 2023.

About The Orange Paper

The Orange Paper is a free publication produced by Synergy Research Group for the pharmaceutical industry since 2007. It pulls together data from numerous public sources into a single brief document to aid decision makers planning to conduct clinical trials.

It is produced quarterly, with an annual summary at the close of each year.

All of the data within this document are actual on date: 03/10/2023

About Synergy Research Group

Synergy Research Group is a contract research organization successfully operating in Russia & Kazakhstan since 2002.

From year to year our company is consistently in TOP-10 of market leaders by the numbers of conducted clinical studies and enrolled patients.

The high recruitment rates of the emerging markets combined with innovative technology allows Synergy to offer our clients conduct faster, more cost-effective studies without sacrificing quality for our clients.

For all of clinical studies conducted by our company we've set up the highest level of world-class quality both for SOPs and for final study data.

We're continuously working on improvements of our SOPs, study risk management and IT infrastructure – and replacing an outdated R&D strategies by novel, more efficient approaches to clinical research.